

K101277
JUN - 4 2010

Future Mobility Healthcare Inc.
FDA Submittal - SPECIAL 510(k)
ORION II (Heavy Duty 350lbs and 500lbs)

510(k) Summary

Submitted by:

Future Mobility HealthCare Inc.
3223 Orlando Drive
Mississauga, ON, L4V 1C5
Tel. (1-888-737-4011)

Contact:

Mr. Abdulsamad Panchbhaya
Toll Free: 1-888-737-4011, Local: 905-671-1661
abdul@future-mobility.com

Date: March 26, 2010

Trade Name: ORION II (Heavy Duty 350lbs and 500lbs) mechanical wheelchair

Common Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical

Predicate Device:

We are making the claim that the modified ORION II (Heavy Duty 350lbs and 500lbs) is substantially equivalent to the predicated device listed in the chart below.

LEGALLY MARKETED PREDICATE DEVICE	MANUFACTURE NAME	REGULATORY CLASS AND PRODUCT CODE	510(k) REGISTRATION NUMBER
ORION II Wheelchair	Future Mobility Healthcare Inc.	Class I/II	K061010

The rationale of declaring the modified Future Mobility HealthCare Orion II (Heavy Duty 350lbs and 500lbs) is substantial equivalent to the above predicate device is based on the following:

- ✓ Same Indications for use: providing mobility to persons limited to a sitting position.

- ✓ Similar key design technical characteristics- The ORION II Medical device and the Orion II (Heavy Duty 350lbs and 500lbs) are mechanical wheelchairs which have technical similarities such as a tilt, and recline capabilities. Both devices contain an adjustable back angle and provide similar performance.
- ✓ The modifications consist of wider frames with a reinforced design to withstand the higher weight capacities of 350lbs and 500lbs. This modification is intended to allow the weight capacity of the wheelchair to increase from 250lbs to 350lbs for the additional widths ranging from 21" to 24", and to 500lbs for additional widths ranging from 24" to 32".

Conclusion:

Future Mobility HealthCare Orion II (Heavy Duty 350lbs and 500lbs) wheelchair was developed in accordance with ISO 7176, parts 1, 5, 7, 8 and 11. It is the conclusion that the Future Mobility HealthCare ORION II (Heavy Duty 350lbs and 500lbs) is safe and effective, as well as substantially equivalent to the legally marketed device identified as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Future Mobility HealthCare, Inc.
% Mr. Abdulsamad Panchbhaya
President & CEO
3223 Orlando Drive
Mississauga, Ontario
Canada L4V 1C5

JUN - 4 2010

Re: K101277

Trade/Device Name: Future Mobility Healthcare Inc. ORION II (Heavy Duty 350lbs and 500lbs)

Regulation Number: 21 CFR 890.3850

Regulation Name: Mechanical wheelchair

Regulatory Class: I

Product Code: IOR

Dated: April 26, 2010

Received: May 6, 2010

Dear Mr. Panchbhaya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

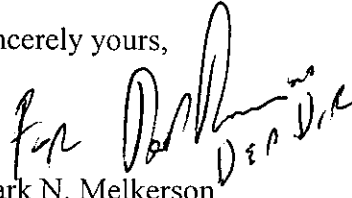
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'for Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): _____

Device Name: Future Mobility Healthcare Inc. ORION II (Heavy Duty 350lbs and 500lbs)

Indication for Use:

To provide mobility to persons limited to a sitting position.

Prescription Use _____

AND/OR


Over-The-Counter Use X

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101277